CERVICAL CANCER ELIMINATION
INTERIM COMMITTEE

House Majority Caucus Room 311
State Capitol
Boise, Idaho

October 11, 2005

M I N U T E S

The committee was called to order by **Co-chair Representative Robert Ring** at 9:30 a.m. Other members present were Co-chair Senator Joyce Broadsword, Senator Kate Kelly and Representative Donna Pence. Staff present were Maureen Ingram, and Charmi Arregui.

Others present were Dan Heincy, R.Ph., Merck Human Health; Dr. Alan Shaw and R. Scott Burns, Merck Vaccine Division; Tom Rosenthal, Medicaid, Department of Health and Welfare; Minnie Inzer Muniz and Jean Scepka, Women's Health Check, Department of Health and Welfare; Scott Pugrud, Connelly and Smyser Ltd; Courtney Washburn, Idaho Women's Network; Molly Steckel, Idaho Medical Association; Brad Hoaglun, American Cancer Society; Bill Foxcroft, Susan Ault, and Jesus Blanco, Idaho Primary Care Association; and Brenda Vanden Beld, Reproductive Health, Department of Health and Welfare.

Senator Kelly moved to approve the minutes of August 9, 2005, seconded by **Senator Broadsword**. The motion passed unanimously on a voice vote.

Ms. Brenda Vanden Beld, Acting Manager, Reproductive Health, Department of Health and Welfare, addressed the role of public health districts in cervical cancer. **Ms. Vanden Beld** emphasized the importance of early detection and treatment for precancerous lesions. Early detection has resulted in a dramatic decrease in the incidence of cervical cancer. She pointed out that it is clearly a concern that those at highest risk for cervical cancer mortality are those with financial and other social barriers to receiving preventive care. Idaho's family planning clinics play a critical role assuring that affordable services are available to those most at risk, such as the under-insured population. She stated that challenges exist for public health districts to decrease gaps in services, which prevent access to preventive care.

Seven health districts operate family planning clinics in 40 of Idaho's 44 counties. Funding for these clinics this year was in the amount of $2.4 million in contract funds received from federal Title X and Maternal Child Health Block Grant funds; district health departments supplement these clinic services with their general funds and local taxes. The majority of these funds, however, must be utilized for family planning services, with cervical cancer screening being only a part of their total program. Other services provided in addition to cervical cancer screening are extensive, including clinical breast exams, sexually transmitted disease and HIV screening, general physical exams, colorectal screening and education, counseling and provision of contraceptive services. The majority of clients who seek care in Idaho's reproductive health clinics are under-insured; 83.6% of the over 30,000 women seen have family incomes which equal or are less than that of 150% of the federal poverty level. In 2004, this meant that their individual income was equal to or less than $13,965 per year. Payment in family

planning clinics is based on a sliding fee scale with no client refused service due to inability to pay. The age demographics of clients seen in the clinics are that of primarily younger women with 75% of women under the age of 30; 63% are between the ages of 18-29 years of age.

In 2004, family planning clinics performed 17,833 Pap smears as well as completing the needed contact and follow-up for both normal and abnormal test results. A combination of traditional, as well as ThinPrep technology, was utilized for these tests, making the cost for each test between $9-$14, which is a discounted rate given by IDX. **Senator Broadsword** asked what percentage of ThinPrep technology is used. **Ms. Vanden Beld** answered that it varies from district to district. Some districts (such as the Central District in the Boise area) use 100% ThinPrep and District Five is considering going to ThinPrep, while other districts remain traditional in their Pap testing procedures, except for using ThinPrep for repeat examinations. **Ms. Vanden Beld** continued, stating that this cost of $9-14 for each test (discounted rate) did not include clinic and administrative costs of follow-up. Therefore, cost calculations for just basic Pap testing in one year fell between approximately $160,000 and $250,000 per year, depending on the type of testing utilized. The health districts currently receive discounted pricing for the cost of these tests, which is likely to increase, as with other health care expenses.

Increasing costs for providing medical care services, along with increasing costs of testing, lead to financial challenges for reproductive health clinics. Federal funding sources for family planning have been flat funded over the last several years and reimbursement by Medicaid only covered the care of 7.1% of the family planning clients in 2004. While health districts are providing extensive Pap smear testing, as well as teaching and education for risk factors for cervical cancer, a significant gap exists in their ability to provide referrals for diagnostics and treatment of precancerous lesions. Although the Pap smear testing can be performed at the health districts on a sliding fee scale, further treatment is often not available at the client's location and the cost of services is often the patient's responsibility. The cost and travel for further treatment is, therefore, a great burden for the low-income and under-insured individuals.

According to IDX data, approximately 12% of Pap smear screenings require some follow-up in the way of a repeat Pap smear, HPV testing, or colposcopy. Considering 17,833 Pap smears, this represents a significant labor and financial effort on behalf of the health districts. In 2004, Idaho statistics indicate that there were 45,622 women 18-64 years of age with incomes below 200% of the federal poverty level. In this same year, family planning clinics saw 24,884 clients in this same age group and income status. This leaves a potential gap of approximately 20,738 women needing care through other sources. Other sources available for these clients within the public health care system include community health centers, as well as the Women's Health Check program (WHC). WHC does provide diagnostic treatment, but primarily serves women 50-65 years of age. This leaves a significant gap in treatment services for the uninsured population who are under 49 years of age within the public health care system.

Ms. Vanden Beld stated that health district administration has made concerted efforts to not only maintain existing services, but also to expand services outside their clinic walls to further identify those at risk for lack of health care services. Special projects that have met with great success for providing cervical cancer screening and education have been in such projects as the Ada County and Nez Perce Juvenile Detention Centers and in the migrant camp near Caldwell. Efforts by public health workers

in just these two groups have not only made much-needed screening more available, but also created the opportunity for education of high-risk individuals, which may lead to the prevention of cervical cancer mortality. In order to ensure a continued decline in the incidence of cervical cancer, further outreach to disadvantaged groups must be continued. This outreach must be in continued accessibility for testing and referrals for early treatment, as well as continued preventive education of high-risk behaviors.

Senator Broadsword commented that if they are having trouble with staffing and funding in order to keep up with testing, if greater awareness through education is accomplished, and if more women then come for testing, can the health districts meet that need? **Ms. Vanden Beld** answered that the need is currently being met because of the federal flat funding, but they have been forced to utilize more of the extra health district general funding and tax dollars to meet those needs. **Senator Kelly** commented that 7% of these clients are covered by Medicaid, and asked why that number is so low? **Ms. Vanden Beld** responded that is due to the number of people who actually qualify for Medicaid; they are probably already set up for different Medicaid sources for getting their family planning, but most are younger women who simply do not qualify. They may have had children and then their Medicaid has been discontinued.

Mr. Tom Rosenthal, Statistician, Medicaid, Department of Health & Welfare, added that a mother has to be in the high 20% to 30% of the federal poverty level to qualify for Medicaid on her own; above that, if she is a pregnant woman with children, she would be covered up to 193%, but above that there is not a lot of coverage. He offered to get more information for the committee on eligibility data. **Ms. Vanden Beld** added that the income to qualify for Medicaid is quite low, so the numbers are quite low.

Representative Ring asked if a woman has an abnormal Pap smear detected in a health district clinic, where are their referral sources, or is this woman sent to a local practitioner? In Ada and Canyon counties he assumed they would be sent to the Family Practice Residency for colposcopy and possible biopsy; how available are local practitioners? There is resistance in obstetrics due to very poor reimbursement and asked if that were true with regard to gynecologic services? **Ms. Vanden Beld** answered that in different health districts in Idaho, unique partnerships have been developed. In Ada county, the partnerships are with the Family Practice Residency Program and Central Health District, which has the capability to do its own colposcopies in their clinics, as does District 3, and they absorb that expense since federal funding will not cover that in their program. District 7's referral base is often to the Family Practice Residency Program in Pocatello, so those clients have to travel for treatment. District 5 negotiates with practitioners within their community; District 1 has grant source money to provide some referrals for their clients.

Senator Kelly asked about resources with regard to prevention and referred to a grant process last year through the family planning bill, legislation that passed the Senate and failed to pass the House. If that legislation had passed and those funds were able to be accessed, would that help address the needs in the health districts? **Ms. Vanden Beld** answered that potentially, yes, it could have helped, but the content of the waiver never has been established solidly up to this point, so that would bring funds; but because the health districts would be listed as only one provider of those services, people would be free to go to any provider they chose.

Senator Broadsword clarified that the family planning bill would have allowed young women, once

they had a baby and had gone back to their ob/gyn, to continue care for the following six months so that they could get family planning counseling and treatment. Such women would not necessarily end up at the health district. They might be with their family practitioner or their ob/gyn doctor. **Representative Ring** commented that due to ways that Medicaid obstetric services are, most people think that would include a six-week checkup after giving birth; however, they only qualify for a six-week checkup if they deliver during the first five to ten days of the month, since they use calendar months. If women deliver a baby, for example, on the 25th of the month, they only have 35 days to get their 40-day checkup, which has been a problem. **Representative Ring** added that the 2005 bill would have allowed a woman to go back to the doctor who delivered her baby to get a six-week checkup and follow-up family planning or contraception counseling, as well as Pap smears and STD checks.

Senator Kelly asked for confirmation that the "7% Medicaid clients" at the health districts are the ones that would actually have benefitted from that extension of the Medicaid benefit. **Ms. Vanden Beld** answered that, depending on the conditions of the waiver, the health districts could potentially benefit from some Medicaid clients who could qualify, as for instance, those with CHIP children. The ideal would be that the parents would be included in this Medicaid waiver program, so some of those parents could be seen by the health districts and that could potentially increase Medicaid funding into the health districts. It all depends on who would be included in the Medicaid waiver plan program. **Dr. Shaw** reiterated that the waiver has not been written; the children are covered up to 185% of the federal poverty level, but the mothers are not. This waiver would look to cover those parents of those children up to 185% of the poverty level on the family planning waiver.

Senator Broadsword asked how many women under age 49 are being missed and not seen by the health districts? **Mr. Rosenthal** answered that he could get that figure for the committee, guessing that the number is about 30,000 to 40,000 eligible women in the 19-44 years of age group.

Mr. Bill Foxcroft, Executive Director, Idaho Primary Care Association, distributed materials entitled *"Community Health Centers (CHCs), Affordable, Quality Health Care for All,"* a copy of which is available in the Legislative Services Office. He stated that ten CHCs operate in 30 Idaho communities providing 50 different programs throughout the state including medical, dental, and behavioral health among others. In 2004, eight CHCs saw 79,869 patients with 280,816 visits; two CHCs were just opened and the statistics for 2004 do not include them. Four more are scheduled to come into operation soon. There are also two mobile clinics that provide dental and medical care in rural areas where transportation is difficult; it is an extensive system and works well to provide access to care. **Representative Ring** added that hopefully there will be another CHC soon in Caldwell. **Mr. Foxcroft** clarified that **Representative Ring** recently donated his medical practice site, for which they are very grateful; hopefully funding can be found to get that site operational.

Mr. Foxcroft stated that CHCs are unique, providing primary and preventive medical, dental, and mental health care, and pharmacies, that are affordable and accessible to all Idahoans, regardless of income or insurance; they provide sliding fees based on incomes. They operate 51% by consumer majority boards. CHCs provide a superior model for chronic disease management and health improvement. CHCs incorporate health education, community outreach and support programs in the clinical practice. CHCs provide formal and informal referral arrangements with community hospitals, other medical providers, specialists, and social service agencies. CHCs maintain partnerships with many other organizations and institutions including Idaho universities, faith organizations, foundations,

the American Cancer Society, local health districts and the Department of Health and Welfare. Three CHCs participate in the 340B pharmacy program to make prescriptions affordable. Several million dollars worth of free prescription assistance is provided to patients yearly. CHCs are in communities that otherwise could not have accessible health care, have staff that are culturally and linguistically competent, incorporate outreach and health education in their scope of services, and provide case management in their scope of services.

Statistically speaking, **Mr. Foxcroft** said that statewide, 57% of Idaho CHC users have incomes below 100% of the federal poverty level; 49% of Idaho CHC users are uninsured; 21% are on Medicaid; 20% have private insurance; 32% of Idaho CHC users are Hispanic/Latino; and 58% of all CHC users are female. In 2004, over 20% of the patients needed interpretation services (primary language other than English). CHCs provide a medical home for uninsured and low-income people and five CHCs are Women's Health Check (WHC) providers. Capacity is becoming an issue; there is a vacant site in Caldwell but there is not funding for services and staff, so funding is another issue.

Ms. Susan Ault, Clinical Services Director, Idaho Primary Care Association informed the committee she is also a nurse practitioner and has worked in reproductive health for many years. She shared data with regard to cervical cancer screening as follows:

Twenty-four percent of female CHC users between the ages of 18 to 44 received a Pap smear in 2004; only 5.7% of CHC Pap smears came back with abnormal cervical findings, a fairly low rate of abnormal findings for Pap smears. In 2004, Idaho CHCs saw 21,367 female users, 80% being over the age of 30 years, a lower risk group for cervical cancer. There were 5,173 Pap smears given, with 296 having abnormal cervical findings. Centers provide case management for abnormal findings and most provide colposcopy and follow-up treatment.

Senator Broadsword wanted to clarify the risk factor versus age issue. Are women under 30 years of age much less apt to end up with cervical cancer than those 30-44 years? **Ms. Ault** answered that women under 30 are at higher risk for HPV which could eventually lead to cervical cancer. **Dr. Shaw** added that the younger a woman is, the more likely she is to have a robust immune response, but the time required to develop cervical cancer is several years generally, so finding cervical cancer is more frequent in older women; finding incipient infection is more common in younger women. **Ms. Ault** confirmed that 80% of the patients, between the ages of 18 and 44, who received Pap smears, were over the age of 30. If those over 30 have not been screened or have risk factors, they are more likely to have cervical cancer, but if they have had screening and negative results, according to protocol, they can have less frequent screening.

Ms. Ault identified barriers to Pap smear screening:

- Transportation - centers have limited funds to pay for transportation and increasing gas prices especially hit rural/isolated communities.
- Cultural issues - centers strive to have culturally competent providers. Thirty-two percent of users are Hispanic and 4% are Native American.
- Low-income women in Idaho and nationally are less likely to have Pap smears than higher income counterparts. Fifty-seven percent of CHC patients have incomes below 100% of the federal poverty level.

Senator Broadsword asked what CHCs do as far as education and building awareness that women need Pap smears, especially among the non-Caucasian, Hispanic and Native American populations? **Ms. Ault** responded that mailers are sent out, and education varies according to resources available in different CHCs. The focus of CHCs is to provide comprehensive primary care, and cervical cancer screening is only a small part of services provided.

Mr. Tom Rosenthal, Research Analyst Supervisor for the Division of Medicaid, Department of Health and Welfare was invited to present figures relating to the amount of expenditures that Medicaid has paid on behalf of recipients who have had a diagnosis related to cervical cancer. He reviewed the paid claims carrying particular diagnosis codes to gather the necessary information; the main limitation with this analysis is that if a claim did not carry the codes in question, even if related to the treatment of the particular disease, he cannot readily retrieve it. Health and Welfare does not have available software that would enable them to better group all claims associated with a particular medical occurrence. A few points he asked the committee to consider were:

- This type of analysis cannot be considered complete without extensive case reviews on the individual recipients.
- **Mr. Rosenthal** had only the claims paid while the individual was covered by Medicaid. If they came from other coverage or acquired other coverage, he did not have those costs available to him.
- If the recipient was over 65 years of age, Medicare would be responsible for most of the treatment costs.

For the purpose of this study, **Mr. Rosenthal** looked at three areas related to cervical cancer: dysplasia, carcinoma in situ, and malignant neoplasms. Dysplasia is an abnormal growth (pre-carcinoma); carcinoma in situ is a cancerous lesion that is still within the top layer of the skin of the cervix and has not spread beyond that; malignant neoplasms are malignancies which have spread into deeper tissues.

Mr. Rosenthal gathered cost and occurrence data by these three areas and looked at the data in two ways:
(1) state fiscal year 2005 only to get an idea of annual cost to the program, and
(2) claims over a five-year period (state fiscal years 2001 through 2005) to get an idea of cost for a recipient over time.

The results are summarized in a handout entitled: "*Table 1 - Results from Medicaid Paid Claims Analysis*," a copy of which is available in the Legislative Services Office. Table 1 contains the following information:

For state fiscal year 2005 only, there were 1,115 recipients who had a paid claim carrying dysplasia as the primary diagnosis, 204 with carcinoma in situ, and 56 with malignant neoplasm. The paid claims totaled $580,000 for dysplasia, $520,000 for carcinoma in situ, and $1.8 million for malignant neoplasms. The total costs that **Mr. Rosenthal** could directly attribute to these three classifications of disease amounted to $2.9 million for state fiscal year 2005.

Mr. Rosenthal then expanded his review to cover a five-year period for each disease classification to

get a better idea what an individual with these diagnoses may cost over time, with the results also included in Table 1. He displayed the recipient counts by dollars expended in frequency distributions in attached graphs. The bottom line of the five-year data was as follows:

- For dysplasia, there were 3,875 recipients with a claim carrying that diagnosis. The dollars paid totaled $3.1 million.
- For carcinoma in situ, there were 617 recipients with claims totaling $3 million.
- For malignant neoplasm, the figures were 157 recipients and $7.6 million.

When looking at the average costs for these three diseases, the frequency distribution is very important, according to **Mr. Rosenthal**, as the data is heavily skewed to the low end. For example, using state fiscal years 2001 through 2005, for malignant neoplasm, of the 157 recipients presenting with that diagnosis, 103 had paid claims associated with this diagnosis of less than $1,000, but one was $624,000. This pattern repeats with the other two disease classifications. Of the 617 with carcinoma in situ, 475 had paid claims of less than $1,000; and of the 3,875 with dysplasia, 3,529 had paid claims of less than $1,000.

The total cost that **Mr. Rosenthal** could directly attribute over this five-year period was $13.6 million in Medicaid expenditures; these were only the costs that Medicaid paid and that he could directly attribute to each disease classification. **Senator Broadsword** reiterated that for just two patients, the state paid over $1 million; the state is paying a lot of money to treat a preventable disease.

In response to a request by **Senator Kelly** for further clarification of interpretation of the graphs and whether or not the women on the lower end of amounts paid for claims had had Pap smears, and to follow up on **Senator Broadsword's** observation that this is a preventable disease, **Representative Ring** responded that if a woman has a negative Pap smear, the chance of having an undiagnosed cancer is minuscule. However, the further an undiagnosed cancer progresses, the more radical and expensive the treatment. Thousands of Pap smears can be funded for the cost of treating just one cancer, so early detection is key to treatment while still curable. **Mr. Rosenthal** added that in 2005, Medicaid spent $440,00 on Pap smears for 5,000 to 6,000 clients, at an average cost of $44 each, and concluded by emphasizing that the total cost that can be attributed to these diagnoses over a five-year period was $13.6 million in Medicaid expenditures.

Dr. Alan Shaw, Executive Director, Virus and Cell Biology, Merck Research, West Point, Pennsylvania, informed the committee he is in charge of the laboratories that developed the vaccine that was discussed in a CNN.com article entitled "*Health - Study: Vaccine blocks cervical cancer,*" a copy of which is available in the Legislative Services Office. **Dr. Shaw** was traveling in the area and came to answer any questions the committee might have. He wanted to explain a little about vaccines, as they apply to public health programs, because we are in a fairly special situation today with the possibility of having a vaccine for cervical cancer. **Representative Ring** commented that he was elated to read in the Wall Street Journal that the first big test was 100% effective in curing HPV, particular strains that are at high risk for cancer. **Dr. Shaw** agreed he was delighted and amazed as well; the vaccine works even better than expected. The easy part, making the vaccine, is done; the hard part is the implementation. **Dr. Shaw** commented that vaccines as a health care delivery modality are somewhat different than the standard treatment kinds of things that are commonly done in medicine, and the fact that they are delivered largely through public health systems gives us a tool to address this

type of cancer problem from an orthogonal perspective. The standard gynecological screening and treatment system we have is highly effective; if you compare the rates of cancer in the United States compared to places where there is not a well organized gynecological system (such as Mexico) the rates vary ten-fold to what is seen in the U.S., which is dramatic. Many testing techniques have improved over the years and are likely to have a big impact on how cervical cancer screening is done; with the advent of vaccines, this provides another tool to address this important problem. A relative truism for vaccine programs as carried out in the United States is that they tend to be levelers of health care disparity, a current example being the chicken pox vaccine, licensed back in 1995. What was seen was that both the morbidity and the mortality dropped across the general population, but if you take out the African American population, they had a much further drop now down to the Caucasian base lines as well. A program applied in childhood really can change the way people's lives develop; with a possible vaccine to prevent STD's, a similar outcome could be possible.

Representative Ring asked when this vaccine may be approved by the FDA. **Dr. Shaw** answered that Merck had filed the chemistry manufacturing and preclinical section with the FDA in September, 2005; the studies are now being written up for submission and Merck hopes to have those studies in by December, 2005, and the FDA has said they would give this a priority review given the novelty and importance of this vaccine. If all goes well, **Dr. Shaw** predicted that a license will be available toward the middle of 2006 for this cervical cancer vaccine.

Senator Broadsword asked if more than one study group was done. **Dr. Shaw** answered that a series of studies were done with particular goals; the ones reported last week in San Francisco were very large, double-blind placebo controlled studies done with women ages 16-24, median age about 20 ½, looking for efficacy against the appearance of cervical inter-epithelial neoplasias of any grade, but keying primarily on grades 2 and 3, so these would be the precancerous lesions, if left untreated, that become cervical cancer. One clinical study was done in a very invasive, aggressive way trying to capture every case of infection and disease, with a full pelvic exam every six months. Another study was done in a more "real-world kind of way," doing annual Pap smears with the normal kind of detection and standard care with the end result being much the same. There was complete protection against the appearance of high-grade lesions, which the FDA has allowed Merck to use as a surrogate for cervical cancer. Another unique aspect of this study was that a large faction of the phase 3 group was enrolled in the Nordic countries of Sweden, Denmark, Iceland and Norway and these four countries have a collective cancer registry where cancers are scored on an individual basis by their equivalent of social security numbers. About 30% to 40% of the population in Merck's study was in these four countries. These women were "front-loaded" into the program, so they are now running about 3-7 years ahead of the anticipated commercial availability of the vaccine for the general public. When and if break-through disease is seen in these nordic countries, that will alert Merck if a booster program should be done. This group of women will be the population used if Merck modifies the vaccine regimen.

Representative Pence asked if **Dr. Shaw** had any idea how long these vaccines will be effective, wondering about the need for booster follow-ups. **Dr. Shaw** stated that is one of the weaknesses in any vaccine program; Merck has four-years of follow-up on their first study done in 1998, and they will continue to be followed; data is accrued as time goes by.

Senator Kelly asked what "genetically engineered" means. **Dr. Shaw** responded that Merck took the

gene for the co-protein of the virus which carries all of the immunological structures that the immune system recognizes; that is taken out of the virus and is put in a yeast, and the yeast cell will then read that information and make the protein. The protein then self-assembles into something that looks very much like the virus, and then that is purified. The result is a virus with no cancer-causing genes in it. **Senator Kelly** asked if there were other vaccines that have been made that way. **Dr. Shaw** responded that yes, the hepatitis B vaccine was the first, and the cervical cancer vaccine was done similarly. There have been twenty years of safety and performance experience with a vaccine made in this way.

Senator Kelly inquired about another vaccine made by a competitor of Merck, asking if the same time-frame for FDA approval would apply to that vaccine? **Dr. Shaw** answered that he thought that Merck was a few months ahead of that competitor; the other vaccine includes types 16 and 18, which account for about 70% of cervical cancer worldwide. Merck's vaccine includes types 16, 18, 6 and 11; types 6 and 11 cause about 90% of genital warts and a fair amount of low-grade cervical inter-epithelial neoplasia. If a woman has visible genital warts and delivers an infant vaginally, the infant's pharynx linings can be affected, resulting in many surgeries to clear these warts from the infant's airway.

Mr. Scott Burns, Health Policy, Merck Vaccine Division, explained to the committee how the HPV virus can be transmitted to a woman who is not promiscuous, explaining that Merck has done studies and shared that data with various groups around the country. Parents who may have to decide what parental guidance to give their daughters regarding this vaccine for cervical cancer need to consider many different things. Even if a woman is virtuous through her entire life, there are circumstances beyond her control that would cause an infection of the HPV virus, so it is important to have a broad-based immunization program. Everyone could potentially be exposed to this virus, even virtuous women. There are a number of things that could happen during adolescence that would be beyond a young woman's control; data suggest that 60% of sexual activity is nonconsensual. A married woman could have a partner who has had even one other sexual partner; that partner puts that woman at risk. With just one partner, a woman has up to a 40% chance of obtaining HPV within the first six months of that relationship. Unfortunately, more than 50% of marriages end in divorce, so a woman who remarries may have a new partner who could have a sexual history that would put her at risk. A woman's husband might pass away prematurely, resulting in the same at-risk situation. Up to 80% of women will get the HPV virus and about 90% of those will be cleared on their own by the woman's own immune system. With an immunization program, many of these women will be protected.

Representative Ring said that as a gynecologist for forty years and as a pragmatist, he has seen many virtuous young women; however, at about age 13 through 17, hormones can take over a young woman's good judgment, even though these young women have been carefully taught and intended to be totally virtuous. Each exposure puts a young woman at risk and **Representative Ring** emphasized that penetration is not necessary for contracting the HPV virus; heavy petting has also been known to transmit the virus.

Ms. Jean Scepka, Clinical Coordinator, Women's Health Check (WHC), Department of Health and Welfare, addressed the committee regarding gaps in health care. She said that WHC sees 3,000 women, adding that their main focus is women ages 50-64. If WHC sees a woman who has a history already of dysplasia, cervical abnormalities, WHC can take women at age 30. There is a cap on the number of women that WHC can see; only 25% of WHC's patients can be in that lower age group. In spite of the work that everyone is doing, and the resources that WHC has, there is still a gap for women

ages 30-50. Of 96 women with precancer or cervical cancer that WHC treated, two women, both 58 years old, had invasive cancer. By the time WHC saw these women, their cancer was invasive. Forty-seven percent of those 96 clients had CIN 3, 20 had CIN 2, 14 had CIN 1, which is the lowest grade. All of these women were over age 30. WHC treated five in situ cancers and the women were all over the age of 40. Forty-five percent of the women diagnosed were from rural, frontier communities. There are 15,828 uninsured women in the group 40-60 years of age. If we look at the 50-64 years of age group, which is WHC's primary target, we see there 7,259 women, with approximately 3,000 of them being served by WHC. Again, I think there is a service gap for the women in the 30-50 age group.

In response to a question from **Senator Broadsword**, **Ms. Scepka** said the Centers for Disease Control (CDC) sets the cap on how many patients WHC can see. She reiterated that the greatest rate of cancers is found in women 50-64 years of age, and that group remains their primary target. The WHC program is fully funded by the federal government. **Senator Broadsword** asked if Ms. Scepka had any suggestions how to reach the women not being served. **Ms. Scepka** noted there is a higher rate of cervical cancer among Hispanic/Latino women who tend to be reluctant to be checked due to cultural factors. Some success, however, has been demonstrated in peer, or one-on-one, education and information sharing.

Representative Ring asked if **Ms. Scepka** has data on women of Hispanic background, noting that the incidence of cervical cancer in Mexico is about 10 times higher than in the United States due to the health system and fewer health checks. **Ms. Scepka** said she did not have the data but noted that the WHC is serving at least, if not more than, the percentage of Hispanics in Idaho.

Senator Broadsword, noting the committee's task is to find options for increasing screening accuracy, said she was personally pleased that many of the health districts are using the new technology. **Representative Ring** supported that comment by pointing out that two districts are only using ThinPrep testing, which, though more expensive, is cost-effective compared to the cost of doing two or three previous smears or performing unnecessary colposcopies and biopsies.A recommendation the committee might consider is encouraging all health districts and community health clinics to consider using ThinPrep technology.

Senator Broadsword said she has been told by some practitioners they use the regular Pap smear when they've had several negatives in a row and don't feel there's as big a chance of a virus being present. It will likely end up that the method used will have to be left to the practitioners' discretion, but that especially for a first-time visit, it would make a lot more sense to use the test that's more accurate. She asked if an accuracy figure comparing methods was available in committee minutes.

Senator Kelly, pointing to the scope of what the committee's review should be, noted that she is not a medical professional and that she would hesitate to put her name on anything that presumed she knew any better than medical professionals implementing care. This vaccine obviously offers promising developments in prevention of HPV and thus cervical cancer, but we as a committee have no basis of evaluating its effectiveness or encouraging its use in advance of FDA approval. There is for her a dilemma about what the committee will put in its report and what actually the committee can do from a legislative standpoint.

Senator Broadsword clarified that the testing methods and the vaccine are separate; the ThinPrep

testing method has been proven much more accurate than the standard Pap smear. **Ms. Scepka** said the traditional Pap is still the gold standard for cervical cancer screening. It's less expensive, and is necessary considering the WHC has limited federal funding. The reason the CDC has had the program remain consistent with using the traditional Pap for most women, is that twice as many women can be screened with that funding. The advantage to the ThinPrep is, if you have a candidate that you want to look at HPV testing, with one sample you can do the Pap and also do the HPV testing; the advantage is in not having to bring the woman back for a separate screening. The traditional Pap is still the gold standard for Pap testing; it is not necessary to use ThinPrep. Some of the rational of those switching to ThinPrep is that it's easier to use one test method and they are getting a break from the laboratories to go with it. But truly the traditional Pap is still a very valid way of doing cervical cancer screening, unless you want to do a triage and look for HPV. From a federal standpoint in funding, we can reimburse for a ThinPrep, but only at a traditional Pap rate. To test only with the ThinPrep method would cut in half the number of women the program could test.

Representative Ring noted that most of his colleagues in private practice determine how to test based on the condition of the cervix upon examination. If no problems are observed during the physical exam, they use the traditional Pap test. Most of those in private practice are doing some of both, using the Pap for low-risk patients, then using ThinPrep for a second exam if one is indicated. There is a lot of room for both methods.

Dr. Shaw said Merck chose to use the ThinPrep system in its clinical study simply because they evaluated both systems and found it to be easier and clearer to read. Since Pap smears were one of the primary end points, they wanted the most robust means of measuring that outcome. He offered to provide further information for the committee to consider regarding the sensitivity and specificity of standard Pap smears versus ThinPreps versus other systems.

Representative Ring noted that the ThinPrep has considerably fewer false negative results than the standard Pap, which can have up to a 40% false negative. Fortunately, the vast majority of them are CIN 1's that are read as normal or just inflammatory. For further discussion, I think we can offer full use of ThinPrep only as an alternative that might be considered. **Senator Kelly** said that depending on how that was worded, it might be something she could support. It should include: (a) The importance of deferring to professional judgment on a case-by-case basis; and (b) Other factors that we might not know about in terms of funding and other restrictions that might make what we might see as a good thing, might end up being not such a good thing. **Representative Ring** said that with several years' experience it does look like the ThinPrep, other than cost, is going to be far superior; again, if you do twice as many with the possibility of missing an occasional lesion. **Ms. Vanden Beld** clarified that the average cost of a ThinPrep is $9 to $14, a discount rate that only the health districts get. Most people pay a lot more.

Senator Broadsword said that the committee's task is to find Idaho's pockets of need, and she thinks the committee has heard very clearly that that is the uninsured, the under-insured and the Hispanic/Latino population in the state. The question becomes "How do we bring this to their attention and get better service in those areas?" Do you as a committee see that there is something we could do through our Health and Welfare Department or at Women's Health Check or other groups to build awareness? I keep going back to maybe public service announcements or just that constant reminder that you do need to get a Pap smear; it is important.

Senator Kelly said she thought at best what the committee could do in a report is to encourage the on-the-ground implementers to do that to the extent their resources allow. We very clearly have seen that prevention is both a fiscally and a medically preferable route. To reiterate that and to say that we would encourage providers to do that, other than that, we don't want to tell them to deflect their existing resources to that, even if we had that authority. We want them to decide how best to spend what little they have — to encourage implementers to educate as their resources allow and that the committee recognizes the value of that. **Representative Ring** noted that it's a lot easier to prevent a health care problem than to treat one after the fact. The more we can prevent, the more money that frees up to prevent more.

Representative Pence said the committee was talking about low income and trying to reach those people. Prevention is mostly covered in insurance policies. In answer to her question about whether Blue Cross and Blue Shield recognize these as valid tests and pay for them, **Representative Ring** answered in the affirmative. She then noted that her HPV test was not paid for by insurance. **Mr. Brad Hoaglun, American Cancer Society**, said that the only screening tests required by the state of Idaho to be covered by insurance companies are mammographies. Everything else is up to the insurance company to determine whether they cover that screening test.

Senator Kelly asked if the Legislature conceivably could require that HPV screening be covered. **Mr. Hoaglun** answered in the affirmative and noted that the American Cancer Society's view is that any test that will screen for a preventable cancer such as cervical or colorectal cancer should be covered. Insurance companies say it would raise rates.

Representative Ring expressed surprise that insurance companies would take that approach because it's been obvious through presentations to the committee that to prevent one or two cancers a year would pay for all the Pap smears done. The possibility of exploring insurance coverage, particularly for colorectal screening and Pap tests, might be something for committee discussion.

Dr. Shaw said that as part of the exercise of educating through the health care system about the HPV virus, they talked to a large number of providers of managed care plans and by and large, the insurance companies do encourage Pap screening. There is some variability in the insurance industry, and even within an insurance company, there are varieties of packages at various levels of completeness, much of which are dictated by what the employer providing the insurance to the individual is willing to pay. As a general trend, there is recognition that screening is valuable and needs to be done and needs to be done regularly and needs to be done well.

Senator Kelly said it would be interesting to know how many states require insurance companies to cover Pap smears. **Senator Broadsword** said it was very possible that they will cover a Pap smear but not necessarily the HPV. **Representative Ring** said he never recalled a patient telling him their Pap test was denied by Blue Cross or Blue Shield.

Senator Broadsword asked **Dr. Shaw** if a woman in her 50's wants to stop getting annual Pap smears and if she has a negative HPV test, is it necessary to get a Pap test every year or two years? **Dr. Shaw** responded that it was very situational, depending on marital status, sexual activity and so forth. I'm not in a position to make Pap screening policy. What I can say, though, given the number of emerging

technologies that are now available or will be available over the next few years, the modalities for cervical screening will change. It's hard to predict just exactly how this all will sort out. We do now have ways of doing better, more precise, more sensitive screening of cervical disease of a variety of types, and we're just going to have to see where the cost and cost-effectiveness lead us — it's not a simple equation.

Senator Broadsword said she thought the committee members were all in agreement that they need to take a proactive approach no matter what it is, rather than waiting to see if it's going to become a problem. While cervical cancer is not a huge problem in Idaho at this time, with the influx of people moving in, the strains of HPV that cause cervical cancer are more apt to move into Idaho in greater numbers. I think it is a wise move to at least continue checking into what technologies are out there and, as a way to stay current, maybe get an annual status report to the germane committees.

Senator Kelly said she doesn't know who it would be reporting to the Legislature, what kind of burden that would place on the provider, and where the information would go and in what context. I don't know if they already do that as a matter of reporting anyway. **Senator Broadsword** noted that **Mr. Richard Schultz**, Administrator, Division of Health, Department of Health and Welfare, said the information is available in the department's statistics, that because cervical cancer is considered an STD, the data is tracked, so I don't know that it would be a burden on the department. **Senator Broadsword** asked **Brenda Vanden Beld** to track down whether it would be an expense to the department to report that information when it does its annual reporting to germane committees. She went on to say that in the education realm, health classes are still required in high school and it might be beneficial to send a little direction to the high school health teachers to at least cover this issue and the importance of getting tested. She noted that she is not a member of the germane Education Committee and didn't know how that might play out. **Representative Ring** said he was on a school board for nine years, and that bringing up anything about sex results in an instant war between the faith-based, abstinence-based programs and the information-based people. It usually brings up a huge firestorm.

Senator Kelly said that having just attended her eighth grader's back-to-school night where his health teacher discussed how they are going to cover these sensitive topics. It was apparent that they have only so much leeway, but certainly a broadly-worded recommendation from this committee that practitioners on the ground, including those in the educational system, have a chance to interact with those who might be at risk for this. We could certainly do something broad like encouraging them to educate to the extent they can within the curriculum and guidelines under which they operate.

Representative Pence said that having had experience as a health teacher in middle school, she didn't have a lot of problems with limitations on giving factual information. She had a lot of leeway, but people had an opportunity to opt out, which some did. She said that in smaller communities people know who's giving the information and they have a lot of confidence that the teacher is going to do a good job. If she were still in teaching, she noted that she would welcome some direction allowing her to cover the screening material. **Representative Ring** said it likely would have to be a policy from a local school board. **Senator Broadsword** said the committee might consider wording a recommendation encouraging local school districts to at least explore the possibility of making sure screening information was included in the curriculum.

Mr. Bill Foxcroft, Idaho Primary Care Association, said that people who are uninsured don't have access to basic preventive services. It might be part of the process to encourage the expansion of insurance coverage to low-income and uninsured people, which the Health Care Task Force has explored. Access to care is a big deal. If you don't have access to care, you don't have access to the basic preventive services.

Senator Broadsword noted that the committee's direction included the identification of priority therapies and preventive vaccines that are effective in preventing and controlling the risk of cervical cancer. She suggested that the committee's report should include that there are vaccines in the testing stage. She also said that she would like to have a report on an annual basis in the germane committee on the progress of all therapies and new technologies. The committee doesn't have to promote any one treatment, but she would like to know what is developing and changing in the field so legislators could assess their need to look at cervical cancer prevention in the future.

Senator Kelly said she thought that such reporting was a question for Mr. Schultz and wondered how many resources it would require from his division. **Representative Ring** said that perhaps a recommendation could be made that the department give the germane committees a report annually on the progress of vaccines and improvements in detection methods. **Senator Kelly** said the information could be included within the department's annual update. **Senator Broadsword** said it was possible the American Cancer Society could also report to the committees on any developments.

Senator Kelly pointed out that lines 22-26 on page 2 of the committee's authorizing legislation asks that more technical findings and medical information be included in the committee's report. She asked how such information could be included in the report. **Maureen Ingram** confirmed that including such technical findings as attachments to the report would certainly be acceptable. **Representative Ring** said that Dr. Parsons, a previous presenter before the committee, as chairman of the Idaho ACOG Society (Ob-Gyn), is an excellent liaison, exceedingly eloquent and knowledgeable.

In response to a question from **Senator Kelly** concerning what the committee's report might look like, **Ms. Ingram** said that while reports vary, staff tries to keep reports condensed and simple, but does what the committee requests. **Representative Ring** said he didn't see any legislation coming out of the committee's work, but noted that further study of the possibility of legislation concerning payment for diagnostic tests had been brought up during the meeting. **Senator Broadsword** made reference to last year's family planning bill as a model for addressing a portion of the problem. After further discussion by the committee, **Senator Kelly** suggested putting language in the report that would encourage accessing particular federal funds that might be available and any others that would similarly expand access to screening. After general agreement among members, **Senator Kelly** agreed to work with Ms. Ingram to draft the language of the committee's report.

Representative Pence said she was very happy with the information that was given to the committee in the course of its work and that the committee needs to find a way to encourage the dissemination of the information to build awareness.

Representative Ring asked if the report should include anything about the Department of Health and Welfare's suggestion of radio and television public service announcements or advertisements about the importance of testing for cervical cancer. The committee agreed that such a proactive approach by the

department was just the kind of education and outreach the committee was encouraging.

Senator Broadsword said she liked **Mr. Foxcroft's** suggestion of increasing the access to care and she thought it would be beneficial to include that in the committee's report — that any increase in the access to care programs would be helpful in combating the overall problem. **Senator Kelly** added that it might be beneficial to mention the work of the Health Care Task Force regarding access. **Senator Broadsword** said the report could note the committee's support of the work that the Health Care Task Force has done. **Senator Kelly** said the Health Care Task Force had heard a proposal for increasing access, but that no action had been taken thus far. She went on to say the report could encourage any efforts by other committees or the germane committees to increase health care access for the at-risk population. **Representative Ring** said that from a tax dollar standpoint, the community health clinics and the Family Practice Residency Program get the most for the tax dollar, by far, in the state.

Senator Broadsword said she was so pleased that there are developments in the vaccine and the new technology coming to light. All the national media coverage of the testing for the vaccine has helped to build awareness.

Ms. Ingram told committee members she would formulate their ideas and findings into a draft report and e-mail it to them for review. **Senator Kelly** said that reference to attachments to be included with the final report would suffice, rather than including attachments with the e-mailed draft.

Representative Ring adjourned the meeting at 11:57 a.m.